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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/390,740 | 02/17/1995 | ROGER COLEMAN | | 7334 |

27904 7590 06/06/2002

INCYTE GENOMICS, INC.
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EXAMINER

MARSCHER, ARDIN H

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1631

28

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/390,740

Applicant(s)

Coleman et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 25, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-60 is/are pending in the application.
- 4a) Of the above, claim(s) 43-45, 48-51, and 55-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 40-42, 46, 47, and 52-54 is/are rejected.
- 7) ☒ Claim(s) 1-39 have been canceled. ~~are objected to~~
- 8) ☒ Claims 40-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 25 & 27
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) ☐ Other:

Upon reconsideration, the after final amendment, filed 7/25/01, has been approved for entry and has been entered. It is deemed to overcome most of the previous rejections of record. It is acknowledged and hereby noted that the Examiner Interview Summary of 8/13/01, previously indicated an agreement to negotiate further so as to fully overcome previous rejections. However, due to significant further issues as summarized below, it has been deemed appropriate to reopen prosecution as summarized below. The response time is restarted as of the mailing date of this office action.

Applicants' arguments, filed 7/25/01, have been fully considered and they are deemed to be persuasive regarding most of the previously set forth rejections. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Unfortunately, upon reconsideration as noted above, the following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Also, due to the newly applied rejections below summarized the Finality of the Office action, mailed 4/23/01, is hereby withdrawn. Also, due to this withdrawal of finality the Notice of Appeal, filed 7/25/01, is deemed moot.

Acknowledgment is hereby made of record of applicants' note regarding the legal decision of *In re Ochiai*, *In re Brouwer*

regarding examination of methods of use of products, if the corresponding product claims are indicated as allowable.

Claims 40-42, 46, 47, and 52-54 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly submitted limitations in the claims directed to "stringent" hybridization conditions has not been found as filed nor pointed to by applicants. This is a specific set of conditions and is not supported, via written basis, by generic hybridization conditions or hybridizability. These limitations are therefore NEW MATTER. Applicants have argued that stringent hybridization conditions are well known in the art and that a definition of temperature or other aspects of this practice do not need to be disclosed for it to be understood as to what is meant. In response this rejection is based on a lack of written description for this limitation in the claims and not on a lack of definition as to what such practice is. It is also noted that other hybridization conditions are well known in the art such as highly stringent hybridization conditions or low stringency conditions. The specific choice of a particular condition as now in the instant claims is the disclosure which lacks written

description as filed. It is noted that applicants have not pointed to any disclosure as filed as to written basis for choosing "stringent conditions" of hybridization regarding the instantly claimed subject matter.

Claims 40-42, 46, and 47 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while providing written description enablement SEQ ID NOs: 1 and 3, does not reasonably provide written description enablement for genomic sequences etc. as summarized below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification discloses SEQ ID NOs: 1 and 3 which correspond to the cDNA encoding the PANEC-1 and PANEC-2 protein species, respectively. It is noted that cDNA cloning resulted in illucidating said SEQ ID NOs: 1 and 3 as given in the instant specification on pages 15-16, but that section V on page 17 lacks disclosure of a full length gene sequence. SEQ ID NOs: 1 and 3 per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, the above listed claims are directed to encompass full gene sequences, sequences that hybridize to SEQ ID NOs: 1 or 3. None of these genomic sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written

description to support the genus encompassed by the claim. Applicants argue that the instant claims do not include claiming of any genomic sequences. In response, the claims include a scope which does, in fact, include such genomic sequences as encoding amino acid sequences and therefore enabling disclosure is necessary to overcome this rejection. Applicants argue that a sequence encoding an amino acid sequence is limited so as to exclude genomic sequences and that such genomic sequences are well known to not be directly translated into proteins. In response, there is no instant claim limitation that requires that the claimed polynucleotide sequences must be directly translated into protein. Rather the limitation in parts a) and b) of claim 40 broadly state that the claimed polynucleotides encode an amino acid sequence. Applicants further argue that, even if the claim wording encompasses an unspliced or incompletely spliced polynucleotide sequence then the hypothetical polypeptide would merely be an artifact or that an intron would comprise a nonsense sequence. In response firstly the claim wording is inclusive of often utilized and well known wording in the art to include genomic sequence. Three example Patents are cited herein wherein genomic polynucleotide sequence is stated as encoding protein even including the presence of introns and exons where appropriate splicing is needed to obtain the mature mRNA for translation. See, for example, Campbell et al. (P/N 5,672,694) at

column 3, lines 13-25, describe nucleic acids which encode the protein β -sacoglycan as including intron-containing genomic DNA sequences. In Campbell et al. (P/N 5,733,732) in column 3, lines 32-39, a genomic DNA library contains clones which encode an adhalin gene. Primers are utilized for PCR amplification which specifically hybridize to intron sequences that flank an exon in order to amplify the exon sequence. Lastly, Liu et al. (P/N 5,837,457) at column 3, lines 10-22, Liu et al. clearly defines a gene or nucleic acid which is either genomic or synthetic which encodes a protein product. Thus, wording regarding encoding a polypeptide or protein as utilized in the instant claims are clearly also utilized frequently in the related art such that a polynucleotide sequence or nucleic acid which encodes a protein or amino acid sequence is inclusive of genomic DNA which encodes said protein or amino acid sequence. Thus, the instant disclosure lacks written basis for polynucleotide sequences which are genomic even though claimed, thus supporting this rejection.

Claims 40-42, 46, 47, and 52-54 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 53, line 3, the citation of "at least 20 contiguous nucleotides" causes the claim to be vague and indefinite as to

what is meant thereby. It may be assumed that these nucleotides are a segment from the target polynucleotide as cited in lines 1-2 of claim 53. But this is not clearly stated as such. Another possible interpretation is that the probe utilized in the claim with the above characterization must be a single polymer without non-contiguous segments such as might be present in a probe which is a mixture of oligonucleotides. Also, the word contiguous is generally utilized to indicate that a segment from another polynucleotide has been selected which is made up of contiguous nucleotides without gaps, deletions, or changes. Clarification of what is meant as to the metes and bounds of the above phrase is requested via clearer claim wording.

Claim 40, part b), is vague and indefinite as to the conflict between the practice of hybridizing under stringent conditions and the phrase "full length". The hybridizing is clearly inclusive of less than 100% hybridization whereas the "full length" limitation indicates 100% hybridization over the entirety or full length of the target polynucleotide. Clarification via clearer claim wording is requested. This unclarity also exists in the other independent claims and dependent claims therefrom due to their dependence.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with


the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 6, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER